APPARATUS FOR DELIVERING AND DEPLOYING AN EXPANDABLE STENT WITHIN A BLOOD VESSEL

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The present application claims the benefit of the filing date of International Application PCT/EP2003/008795, filed August 7, 2003, which claims priority from European application 02017696.2, filed August 7, 2002.

FIELD OF THE INVENTION

[0002] The present invention relates to an apparatus ~~a system~~ for delivering and deploying an expandable ~~a~~ stent ~~into~~ within a blood vessel for use ~~e.g. by a physician in a well-known manner for supporting and/or~~ in reinforcing the vessel walls and maintaining the vessel in an open, unobstructed condition. ~~It is well known in the prior art that the stent can be covered and secured in a catheter by a sheath during tracking and delivery in a blood vessel.~~

BACKGROUND OF THE INVENTION

[0003] ~~Furthermore, it is known that the sheath is retracted before positioning the stent within the vessel. A stent delivery system according to US~~ United States Patent No. 6,168,617 discloses a stent delivery system comprising ~~comprises~~ a catheter ~~with~~ having a balloon for inflating a stent, which is covered having during delivering ~~by a sheath~~. The sheath is axially moveable on the shaft of the catheter and can be retracted in the proximal direction ~~by pull-back means~~.

[0004] ~~US~~ United States Patent No. 5,113,608 discloses a stent delivery device ~~which comprises~~ comprising a hydraulically actuated retractable sheath. Specifically, a pressurising fluid is ~~either~~ supplied by an inflation volume to a portion of a piston housing (or is withdrawn from a portion of the piston housing), thereby actuating ~~a~~ the piston and causing the sheath to retract. ~~As the piston moves the sheath is retracted.~~

[0005] ~~It is the object of the invention~~ In view of the above, it would be desirable to provide an improved stent delivery system ~~with~~ having a protection sheath on the stent to simplify handling of the stent ~~wherein its handling is simplified~~.

~~The object is achieved by the features of the claims.~~

~~In order to achieve the object, the invention is based on the following basic ideas.~~

SUMMARY OF THE INVENTION

[0006] In view of the foregoing, it is an object of the present invention to provide an improved stent delivery system having a protection sheath on the stent to simplify handling of the stent.

[0007] These and other objects of the present invention are accomplished by providing a device for retracting the sheath that is coupled with a fluid pressure device for ~~the~~ inflation and deflation of expandable ~~means (~~balloon~~)~~ for deploying the stent. A pressurised fluid~~,~~ ~~e.g. a liquid or gas,~~ is supplied from the fluid pressure device to the retraction device ~~and causes~~ to cause the retraction of the sheath. After or during the retraction of the sheath, the pressurised fluid in is directed to the expandable ~~means~~ balloon for expansion and deployment of the stent. ~~According to the invention, the~~ The expansion of the stent is controlled by the position of the piston within ~~the~~ a cylinder. ~~Thus, an automatic inflation of the expandable means after orduring retraction of the sheath can be achieved.~~

~~The invention has the following advantages.~~

[0008] The protection sheath is withdrawn by activating the fluid pressure device, which also controls the expansion of the stent ~~by means of the expansion means~~. Advantageously, the protection sheath prevents problems associated with bi-stable stent designs, such as stent-loss and pop-open. ~~Furthermore, stent-loss and pop-open by using bi-stable stent designs such as Biflex stents do not occur. There is also~~ Additionally, there is no flaring of stainless steel stents and no significantly increased profiles ~~(sheath thickness 0,01 to 0,02 mm).~~ If a drug coated stent is used, there will be substantially no drug loss ~~no drug will be lost~~ during handling.

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

[0009] Further features of the invention, its nature and various advantages will be more apparent from the accompanying drawings and the following detailed description of the preferred embodiments, in which:

[0010] FIGS. 1a and 1b are a schematic diagrams of an embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention;

[0011] FIG. 2 is a cross-sectional view of another embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention;

[0012] FIGS. 3-10 are cross-sectional views of the apparatus of FIG. 2, showing steps of the method of operation of the apparatus;

[0013] FIG. 11 is a cross-sectional view of a further embodiment of the apparatus for delivering and deploying an expandable stent within a blood vessel, according to the present invention; and

[0014] FIGS. 12-19 are cross-sectional views of the apparatus of FIG. 11, showing steps of the method of operation of the apparatus.

~~Fig. 1a is a schematic illustration of a first inventive embodiment,~~

~~Fig. 1b shows the partial proximal end of the cylinder 15 in Fig. 1a after retraction of the sheath,~~

~~Fig. 2 is a schematic illustration of a second inventive embodiment,~~

~~Figs 3-10 show steps of the method of operation of the second inventive embodiment,~~

~~Fig. 11 is a schematic illustration of a third inventive embodiment, and~~

~~Figs 12-19 show steps of the method of operation of the third inventive embodiment.~~

DETAILED DESCRIPTION OF THE INVENTION

[0015] ~~In the first inventive embodiment of Fig.~~ Referring to FIG. 1a, sheath 1 is arranged on stent 2 and supported by expandable ~~means 3, preferably an inflatable~~ balloon 3. The ~~arrangement 1, 2 and 3 is~~ sheath, stent and balloon are supported by a catheter (not shown) and inserted into a blood vessel. ~~Furthermore, a~~ Ssheath retraction device (5~~ to~~ 9, ~~11 and~~ 13~~ to~~ 15) and ~~a~~ fluid pressure device (11~~ to~~ 14) are connected with the sheath, stent and balloon ~~arrangement 1 to 3~~ by ~~a~~ wire 4 and ~~a~~ tube 10~~, respectively~~. Particularly, ~~The~~ wire 4 connects ~~the~~ sheath 1 with ~~a first~~ piston 5 disposed in ~~a~~ cylinder 15 comprising ~~a~~ cylinder housing 9. ~~A~~ Hhook 6 is connected at the proximal side of ~~the~~ piston 5.

[0016] ~~The~~ Ccylinder 15 further comprises ~~a~~ floating ~~second~~ piston 7 ~~with~~ having ~~an~~ opening 18, which can be penetrated by ~~the~~ hook 6. ~~The~~ Ffloating piston 7 closes ~~an~~ outlet 17 in ~~the~~ cylinder 15. ~~The~~ Ttube 10 connects ~~the expandable means~~ balloon 3 with ~~a~~ tube 16

mounted at ~~the~~ outlet 17 of ~~the~~ cylinder 15. ~~A~~ Ttube 14 is connected to an inflation/deflation device schematically shown as double-arrow 13 at ~~the~~ one end and via ~~a~~ unidirectional valve (check valve) 11 with ~~the~~ cylinder 15 at the other end. ~~Furthermore, the~~ Ttube 14 is connected via ~~a~~ unidirectional valve (check valve) 12 with ~~the~~ tube 10.

~~The first inventive embodiment operates as follows:~~

[0017] In ~~the arrangement of Fig. 1a the~~operation, ~~expandable means~~balloon 3 is in a deflated state and ~~the~~ sheath 1 covers ~~the~~ stent 2. ~~The~~ Ffloating ~~second~~ piston 7 is positioned so that ~~the~~ opening 17 of ~~the~~ cylinder housing 9 ~~and, thus, the tube 16 are~~ is closed. An operator such as a ~~(~~physician~~)~~ applies pressure from ~~the~~ inflation/deflation device 13 to ~~the~~ tube 14. The pressure shuts ~~the~~ unidirectional valve 12 and opens ~~the~~ unidirectional valve 11. Thus, the pressurised fluid flows into ~~the~~ cylinder 15 and shifts ~~the first~~ piston 5 with ~~the~~ wire 4 and ~~the~~ sheath 1 in the proximal direction~~, i.e. the~~ such that sheath 1 is retracted from ~~the~~ stent 2. The pressure necessary for moving ~~the~~ piston 5 preferably is very low.

[0018] When ~~the first~~ piston 5 reaches ~~the~~ floating ~~second~~ piston 7, the proximal end of ~~the~~ wire 4 with ~~the~~ hook 6 penetrates ~~the~~ opening 18 in ~~the~~ piston 7, and ~~the~~ piston 5 ~~moves the~~ forces piston 7 to move proximally ~~the proximal end of the cylinder 15~~. ~~Thereby~~At the proximal end of cylinder 15, ~~the~~ hook 6 engages ~~the~~ hook holder 8 ~~wherein~~ such that ~~the~~ piston 5, ~~with the~~ wire 4 and ~~the~~ sheath 1 ~~is~~ are fixed at the proximal end, as depicted in FIG. 1b. ~~This fixed position of the pistons 5 and 7 is shown in figure 1b.~~ In this position, the sheath is completely removed ~~(not shown)~~ from the stent ~~2~~, and ~~the~~ outlet 17 of ~~the~~ cylinder 15 is open towards the cylinder chamber.

[0019] In operation ~~this manner~~, ~~the~~ pressurized fluid from ~~the~~ inflation/deflation device 13 flows via ~~the~~ tube 14 ~~and~~ into the left side of ~~the~~ cylinder 15. From the cylinder, the pressurized fluid flows through ~~the~~ outlet 17, ~~the~~ tube 16 and ~~the~~ tube 10 to ~~the expandable means~~balloon 3, ~~inflates it and deploys the stent 2.~~ The pressure is applied until a ~~required~~ predetermined stent diameter is achieved ~~reached~~. Then, the operator applies ~~a vacuum~~ suction from ~~the~~ inflation/deflation device 13 via ~~the~~ unidirectional valve 12 and ~~the~~ tube 10 to ~~the expandable means~~ balloon 3. During ~~this~~ suction, ~~the~~ unidirectional valve 11 is closed. At the end of the stent delivery and deployment process, the catheter ~~with the expandable means and the sheath~~ is removed from the blood vessel and the stent remains in the desired position within the blood vessel.

[0020] Referring to FIG. 2, according to another embodiment of the invention, ~~In the second inventive embodiment of Fig. 2 as in Fig. 1a, a~~ protective cover sheath 101 is arranged on ~~a~~ stent 102, which is supported by ~~an~~ expandable balloon ~~means~~ 103 ~~being an inflatable balloon~~. ~~As in Fig. 1a, the arrangement 101, 102 and 103 is~~ Similar to the embodiment of FIG. 1, sheath 101, stent 102 and balloon 103 are supported by a catheter (not shown), which ~~and~~ is inserted into a blood vessel. Sheath 101, stent 102 and balloon 103 are ~~The arrangement 101, 102 and 103 is~~ connected via ~~a~~ pull-wire 104 to ~~a~~ cylinder-piston arrangement (105, 106, 108, 110, 110a, 112 and 114).

[0021] With further reference to FIG. 2, t~~T~~he cylinder-piston arrangement is connected to an inflation/deflation device that is schematically shown as ~~an~~ arrow 113. ~~A~~ P~~p~~iston 105 with ~~a~~ connector ball 106 is arranged in the cylinder ~~115~~ at its distal end 115a. ~~The~~ W~~w~~ire 104 is fixed at the piston. Receiving socket 108 is located a~~A~~t the proximal end 115b of ~~the~~ cylinder 115. ~~a receiving socket 108 is located, into which~~ T~~t~~he connector ball engages receiving socket 108 when the piston arrives at the proximal end~~, i.e. the right-hand side in Fig. 2,~~ of ~~the~~ cylinder 115. ~~Furthermore,~~ T~~t~~he cylinder-piston arrangement further comprises ~~a~~ unidirectional valve 112, fluid pressure lines 114, 110, 110a and ~~an~~ inlet/outlet 117 ~~as connection to the~~ for inflation/deflation device 113.

[0022] Referring to FIGS. ~~With respect to Figs~~ 3-10, the steps of operation of the ~~second inventive~~ embodiment of FIG. 2 are ~~shown~~ now described. ~~In the second and subsequently in the third inventive embodiment, the fluid F is illustrated by black colour.~~

[0023] Referring to FIG. 3 ~~Firstly~~, vacuum from ~~the~~ inflation/deflation device 113 is employed ~~applied (Fig. 3) in order~~ to purge air from the catheter and the sheath retraction apparatus. In this state, ~~the~~ unidirectional valve 112 is opened and all parts of the apparatus are in connection with the vacuum. After removing the air from the apparatus, pressurized fluid F (e.g., liquid) is introduced from ~~the~~ inflation/deflation device 113 via ~~the~~ inlet/outlet 117. The fluid is shown in black in the figures for illustrative purposes only.

[0024] Referring to FIG. 4, t~~T~~he force of pressurized fluid F shuts ~~the~~ unidirectional valve 112, and fluid F enters ~~the~~ cylinder 115 at its distal end 115a behind ~~the~~ piston 105 ~~(i.e. at the left-hand side of the piston in Fig. 4)~~. Referring to FIG. 5, t~~T~~he force of pressurized fluid F moves ~~the~~ cylinder 105 in the proximal direction ~~wherein~~ such that ~~the~~ wire 104 retracts ~~the~~ protective cover sheath 101 from ~~the~~ stent 102 ~~(arrow A in Fig. 5)~~. During this procedure, the liquid preferably is prevented from entering the catheter and the

~~expandable means 103~~ balloon.

[0025] Referring to FIG. ~~As shown in Fig.~~ 6, after arrival of ~~the~~ piston 105 at ~~the~~ proximal end 115b of ~~the~~ cylinder 115, ~~the~~ cover sheath 101 is completely removed from ~~the~~ stent 102, ~~the~~ connector ball 106 is engaged in ~~the~~ receiving socket 108. ~~and a~~ Also, opening 110a, which penetrates the cylinder wall to the fluid pressure line 110, is opened. The pressurized fluid ~~F from the inflation/deflation device 113 via the line 114 and the cylinder 115~~ enters ~~the~~ line 110 and inflates the balloon ~~expandable means 103~~, as depicted in FIG. 7 ~~(Fig. 7)~~.

[0026] Referring to FIG. 8, t~~T~~he ~~expandable means (~~balloon~~) 103~~ expands and ~~the~~ stent 102 is deployed and contacts the wall of the blood vessel ~~(Fig. 8)~~. Thereafter, the fluid is withdrawn and a vacuum is again applied by means of ~~the~~ inflation/deflation device 113 to deflate the balloon while ~~the~~ piston 105 and ~~the~~ cover sheath 101 remain fixed, as depicted in FIG. 9. ~~(Fig. 9)~~. Referring to FIG. 10~~In Fig. 10~~, the system is fully purged of fluid ~~(e.g. liquid)~~ and ~~the~~ balloon 103 can be re-inflated if necessary, or the ~~expandable means~~balloon and sheath may be removed from the blood vessel while the stent remains in the desired position within the blood vessel.

[0027] Referring to FIG.~~Fig.~~ 11, a further embodiment of the present invention is described ~~shows a third inventive embodiment, which differs from the first and second embodiment in the structure of the cylinder-piston arrangement~~. ~~A~~ T~~t~~wo-position valve 207 is located in ~~the~~ cylinder 215, wherein~~; the~~ valve 207 abuts ~~via a~~ spring 207a disposed at the proximal end 215b ~~(right-hand side in Fig. 11)~~ of ~~the~~ cylinder 215. In the illustrated embodiment ~~position shown in Figs 11 to 14~~, ~~the~~ valve 207 shuts ~~two~~ a pair of channels 216a, 216b, which penetrate the wall of the cylinder 215.~~;~~

[0028] Cchannel 216a connects ~~a~~ fluid pressure line 214 ~~from the fluid pressure device 213~~ with ~~a~~ fluid pressure line 210, which supplies ~~applies~~ the fluid pressure to ~~the expandable means (~~balloon~~)~~ 203. When the piston 205 ~~starting from the space 215a at the distal end of the cylinder 215 arrives~~ is disposed at ~~the~~ two-position valve 207, it pushes the valve proximally ~~(to the right in Fig. 15)~~ and opens ~~the~~ channels 216a and 216b. Thus, pressurized fluid F from ~~the~~ inflation/deflation device 213 enters ~~the~~ balloon 203 via ~~the~~ line 214, ~~the~~ channels 216a and 216b and ~~the~~ line 210 ~~(Figs 15 to 17)~~.

[0029] Referring to FIGS. 12-19, t~~T~~he steps of the method of operation of the ~~third inventive~~ embodiment of FIG. 11 are now described ~~shown with respect to Figs. 12-19~~.

[0030] InitiallyBefore operating, a vacuum is applied in order to purge air from the catheter and the sheath retraction apparatus by means of the inflation/deflation device 213. Thereby Specifically, the unidirectional valve 212 is opened and the unidirectional valve 211 is closed so that space 215a at the distal end of the cylinder 215 at the left-hand side of the piston 205 remains open (Fig. 12). Referring to FIG. 13In Fig. 13, while unidirectional valve 212 and channels 216a and 216b are closed, pressurized fluid F from the inflation/deflation device 213 enters the space 215a of the cylinder 215 behind the piston 205 via the line 214 and the unidirectional valve 211, while the unidirectional valve 212 and the channels 216a and 216b are closed. Thereafter, the piston 205 moves in the proximal direction, (to the right in Fig. 14) and withdraws the thereby retracting protective cover sheath 201 from the stent 202 in the direction of arrows A, as depicted in FIG. 14 (Fig. 14).

[0031] Referring to FIG. 15, aAfter the protective cover sheath 201 is fully retracted, the piston 205 pushes the valve 207 into an open position against the force of the spring 207a into an open position, and the connection between the line 214 and the line 210 via the channels 216a and 216b is opened (Fig. 15). Referring to FIG.As shown in Fig. 16, pressurized fluid F flows via the line 214, the channels 216a and 216b and the line 210 to the balloon 203. While the unidirectional valve 211 remains open and pressurized fluid F acts against the piston 205 and pushes it to the right in Fig. 17, the two-position valve 207 remains in its the open position. Referring to FIG. 17, The balloon 203 expands in the direction of arrows B and the stent is deployed such that it (Fig. 17) and contacts the wall of the blood vessel (not shown).

[0032] Thereafter, vacuum is again applied from the inflation/deflation device 213 and the balloon 203 deflates in the direction of arrows C, as depicted in FIG. 18 (Fig. 18). The unidirectional valve 211 is closed and the pressurized fluid behind the piston 205 acts on the piston 205 such that the piston 205 and the sheath 201 remain fixed (Fig. 18). Referring to FIG.In the final state shown in Fig. 19, the catheter is fully purged and the balloon can be re-inflated if necessary. The pressurized fluid F holds the two-position valve 207 open and locks the sheath 201 in the retracted position. If the retraction apparatus will be used one time only, it can be removed. However, iIf the retraction apparatus will be re-used, the fluid F is purged from the cylinder 215 by opening the unidirectional valve 211 and pulling the piston 205 to the distal end 215a.

[0033] The fluid pressure for operating the retraction device and the expandable means

can be controlled in such a manner that the retraction device and the ~~expandable means~~balloon work concurrently or sequentially~~, e.g.~~ in order to control the correct position of the stent.

[0034] According to a preferred implementation of the invention, ~~It is an essential feature of the invention that~~ the retraction of the sheath ~~1, 101 and 201, respectively, namely at the end of the retraction step,~~ automatically controls the deployment ~~(expansion)~~ of the stent ~~2, 102 and 202, respectively~~. Therefore, a~~A~~n operator ~~can~~ may ~~easily~~ deploy ~~a~~ the stent ~~with a protection sheath simply~~ by activating the inflation/deflation device.

ABSTRACT OF THE DISCLOSURE

[0035] ~~An improved~~ Aapparatus for delivering and deploying~~ment of~~ an expandable stent ~~with~~ having a protection sheath within a blood vessel is provided. The ~~system~~ apparatus comprises a fluid pressure device ~~which~~ that is coupled with a retraction device for the protection sheath, wherein ~~such~~ the stent is automatically deployed by the fluid pressure device ~~that~~ after retraction of the protection sheath~~ the stent is automatically deployed by the fluid pressure device~~. ~~The advantage of the invention is an easy and simple operation of the apparatus.~~